REMARKS

Claims 1-19 remain in this application. Claims 1 and 16 have been amended to more clearly claim the invention. Claims 17-19 have been added. No new matter has been added.

In the Official Action dated August 13, 2002, the Examiner rejected claims 1-14 under 35 USC §103(a) as being unpatentable over Orejola (U.S. Patent No. 4,985,014) in view of Schock (U.S. Patent No. 5,254,097). Furthermore, claims 15-16 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Orejola in view of Schock and further in view of Buckberg (U.S. Patent No. 5,011,469). Applicants respectfully traverse these rejections.

Among other elements, independent claims 1 and 16 each claim: (a) a return cannula having an elongated cannula body having a distal end adapted for positioning in a blood vessel and a return lumen in the cannula body; (b) a catheter port at the proximal end in communication with the return lumen and adapted to removably receive a catheter therein; (c) an occlusion catheter slidably and removably positioned through the catheter port and the return lumen; and (d) an expandable occlusion member attached to the occlusion catheter, the occlusion member having a collapsed configuration adapted for introduction through the return lumen and an expanded configuration adapted for occlusion of the ascending aorta between the coronary ostia and the brachiocephalic artery.

Newly added independent claim 17 claims a cardiopulmonary bypass catheter system that includes a return cannula having a lumen adapted for flowing blood therethrough, and an occlusion catheter sized and configured to be slidably positioned through the return lumen. The occlusion catheter has an occlusion member that has a collapsed configuration adapted for introduction through the return lumen and an expanded configuration adapted for occlusion of the ascending aorta between the coronary ostia and the brachiocephalic artery.

Applicants respectfully submit that neither Orejola, Schock or Buckberg teach or disclose the claimed invention either alone or in combination. Orejola describes two types of ventricular assist devices. In one the right ventricle of the heart is relieved of its work load by a catheter that withdraws blood from the right ventricle and delivers blood to the pulmonary artery. To position the catheter in the right ventricle, the catheter includes a small 2 cc inflatable balloon. The balloon is deflated when introduced into the femoral vein and inflated once in the vein to float the balloon and catheter to the correct location, the right ventricle of the heart. See col 3:35-65. The balloon ***is not*** adapted for occluding the aorta as is claimed in

each of the independent claims of this application. The purpose of the balloon of Orejola is to float the distal end of the catheter into the appropriate location via the natural blood flow. As a result, the balloon is sized so as ***not to occlude any blood vessel.*** If it was such a size, it would not be able to act to flow direct the balloon into the right ventricle. Instead, it is intended to relieve the heart of its pumping load by withdrawing blood to pass it through a roller pump and deliver it to the pulmonary artery.

The Examiner further states that the occlusion catheter is slidably and removably positioned through the catheter port (via Seldinger techniques). Applicants respectfully disagree. Applicants submit that Orejola does not teach or suggest a balloon catheter adapted to be slidably positioned within a return lumen. First, the only balloon catheter shown in Orejola is not adapted to return blood to the aorta. Instead, it is adapted to withdraw blood from the right ventricle. Second, as is described at column 3, lines 35-36, and shown in some detail at Figure 4, the inner tubing 40 and air conduit 42 do not slide within tubing 16. Instead, inflow terminal 38 seals the end of the outer tubing 32 around the inner tubing 40 and conduit 42.

Thus, Orejola does not teach or suggest either a balloon catheter that is slidable within a lumen of a return cannula or a balloon that is adapted to occlude the aorta.

In addition, neither Schock nor Buckberg teach or disclose a balloon catheter that is slidable within a lumen of a return cannula or a balloon that is adapted to occlude the aorta. As a result the combination of Orejola and Schock and Buckberg do not disclose or teach the elements of independent claims 1, 16 or 17. As to the contentions made by the Examiner regarding obvious design choice with respect to claims 3-5 and 9-11, for example, Applicants respectfully disagree with those contentions and reserve the right to contest those points should it become necessary. Accordingly, Applicants request that the Examiner withdraw the 103(a) rejections.

In view of the above, Applicants respectfully submit that this application is in condition for allowance. If the Examiner believes that a telephone conference with Applicants' agent would be advantageous to the disposition of this case, the Examiner is requested to telephone the undersigned.

Respectfully submitted,

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